MICROSTIMULATORS AND MICROTRANSDUCERS FOR FUNCTIONAL NEUROMUSCULAR STIMULATION

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ABSTRACT

During the last Quarter the direct work on micromodules development has been limited to the A.E.Mann Foundation and the Pritzker Institute; Queen's University has continued work on the external controller.

At the Foundation, the focus was on the hermetic glass microcapsule development using an infrared laser. A major effort was expended dealing with the new microstimulator chip development, and in correcting the silicon foundry errors via chip microsurgery.

At the Pritzker Institute, the work centered around the repeater chip revision, the supervising of the first microstimulator wafer rework and the new microstimulator package development. In addition, a patent application has been filed for the suspended carrier modulation technique.

The contribution of the Queen's University is a Microstimulator Bedside Controller Manual, as an appendix.

INTRODUCTION

We are developing a family of implantable micromodular devices for use in functional electrical stimulation (FES) for various clinical applications, including reanimation of paralyzed limbs.

These devices fall into two categories:

1. Microstimulators that generate precisely metered, highly localized electrical pulses.
2. Microtelemeters that digitize and transmit data from bioelectrical sources and transducers.

Large numbers of these devices can be implanted and controlled by a single, external coil that transmits power and command signals by inductive coupling from a highly efficient power oscillator and modulator circuit in a wearable control box. The devices generally consist of a microcoil wound on a ferrite core, a custom IC chip, and a glass cylindrical capsule (approximately 2 mm diameter by 10 mm long) which may contain glass-to-metal feed-throughs for electrodes at the ends.

This contract is concerned with the further development and in vitro testing of the microstimulator package and specialized electrodes that store energy for stimulus pulses in an electrolytic capacitor consisting of anodized tantalum, activated iridium and the intervening body fluids. It also requires the development of a transducer suitable for sensing the angle of the wrist and the development of a microtelemetry module for outward transmission of this signal.

Work at the Alfred E. Mann Foundation

During the first quarter of the renewed contract, the work at the Alfred E. Mann Foundation concentrated around further sealing apparatus development and the improvement of glass to glass and glass to metal sealing techniques using an infrared laser as a focused heat source.

Cleaning and Aligning of the Laser Beam

During the initial tryouts of the infrared laser we were performing relatively undemanding procedures such as sealing a glass bead to a metal feedthrough. When experimenting with more difficult seals, e.g. the glass bead to glass capillary seal, a double weld was observed which suggested a split laser beam. We investigated the phenomenon and found out that at higher power settings the laser develops a side lobe. The manufacturer confirmed the appearance of the side lobe but claimed that only about 5% of the total energy is contained in it. To constrain the beam to a single spot, a 3 mm diameter aperture was introduced into its path which cut off the side lobe.

Once having the aperture in place we decided to add a variable size iris into the path of the laser. The opening of the iris can be adjusted between 1 mm and 7 mm. Its purpose is to improve the laser beam alignment. The red laser that is used to indicate the position of the invisible infrared beam is a diode laser and its output is a short red line rather than a circle. When closing the variable iris, the red line is reduced to a red dot which makes the beam alignment much easier and more accurate than previously attainable.

The experiments performed in the last quarter were directed towards the perfection of the tantalum stem to glass bead seal. In the past, this seal has been

particularly questionable because of the longitudinal grooves on the tantalum wire which constituted leakage paths. The solution has been polishing of the wire which removed the grooves and improved hermeticity. However, stem polishing reduced the tantalum stem diameter and, because polishing compounds are used, introduces foreign material into the tantalum capacitor slug. This may increase the tantalum capacitor leakage current and reduce the capacitance. To eliminate the polishing procedure, we examined tantalum wire from several vendors. Glass seals were made using unpolished tantalum wire, considerably smoother than the one used in current tantalum capacitors. The results were encouraging, the leakage rates being within the noise level of our helium leakage testing machine (less than 10^{-9}). The leakage rates for glass to Pt/Ir wire or glass to Pt/Ir tube were within the same limits.

Glassblower's Lathe Centering Plate

It has turned out that the concentricity of the two chucks on the glass sealing machine (or glass blower's lathe as we will call it from here on) was not as good as believed earlier. A centering plate has been added to the lathe which enables concentricity adjustment. The "stable" stepping motor has been repositioned and a flexible joint now connects the motor and the "stable" chuck. The concentricity is obtained by two mutually perpendicular eccentric pegs that allow the movement of the chuck independently in "x" and "y" directions.

Glass Capillary Cutting

A new approach has been taken on cutting the glass capillaries that provide the protective shell of the microstimulator. In the past, the capillaries have been cut by scribing and breaking. The cut was uncertain, often jagged or

cracked. We now use a silicon wafer dicing machine with exposed grinding disks that are capable of cutting glass capillaries with accuracies to within a thousandth of an inch.

Dummy Microstimulator

To verify the assembly process and the glass sealing techniques, a dummy microstimulator has been fabricated. A microstimulator chip from the first microstimulator wafer run has been used, all the procedures implemented followed the new assembly rules. Figure 1 shows a composite picture of the microstimulator without the iridium washer welded to the vent Pt/Ir tube. Even though no particular attention was placed on hermetic sealing, the helium leak test resulted in 0.55×10^{-9} leak rate.

Silicon Foundry Iterations

A new, corrected layout was sent to the foundry for another run of wafers.

When the wafers were returned it was quickly observed that they did not work. DC current consumption was high and there was no sign of proper circuit response to input signals.

Using a technique described in an earlier report, a temperature sensitive liquid crystal layer was applied to a chip. This revealed localized heating in a spot that strongly suggested that there were high impedance conductive paths between traces on the Poly 2 conductor layer.

Using this clue, other Poly 2 areas were checked for such shorts. It was observed that two Poly 2 lines crossing a common Poly 1 area were connected by a resistance of about 3000 ohms per micron of separation. This almost certainly resulted from a thin "stringer" of Poly 2 along the edge of the Poly 1 area. Such a stringer can result from incomplete etching during the patterning of the Poly 2 layer (Fig. 2).

The design rules provided by the foundry allowed the structure that caused the shorts, in fact the wafers included a test device to detect such shorts. When the test device was checked, it showed the shorts to be present in the processing. The foundry indicated that they were having trouble with the Poly 2 etching process, so we decided to avoid the problem by changing the layout.

The offending geometry was found in the layout in several places in the bias generation and data filtering circuitry, and a modified layout was created to eliminate the problem in those places; another run of wafers was started with the corrections.

In parallel with the new wafer run, 5 chips were sent out to have the stringers cut using an ion-beam micro cutting and patching process. When these modified chips were tested it was observed that the DC current consumption was reduced to expected levels, but the circuits still did not function properly.

Probing of various circuits revealed that the clock comparator circuit was only generating proper output for a few microseconds after the carrier was turned on.

Further probing showed that the bias signal which controlled operating current for the clock comparator was dropping shortly after the data carrier started. This finally was traced to another short due to a Poly 2 stringer: The

presence of clock pulses released the power-on reset signal, but this signal was routed by a Poly 2 stringer which allowed an unwanted current to flow in the bias circuit, thus shutting it down.

This new stringer location had not been corrected in the new layout! Fortunately, a call to the foundry determined that the wafers were still at a point where the problem could be corrected. Three layout layers (Metal, Contact, Poly 2) were changed and quickly sent to the foundry.

Work at the Pritzker Institute

During the past Quarter work at the Pritzker Institute has focussed on 3 areas. First, the design of the Repeater Chip was revised. Second, a plan was devised to rework wafers from an earlier microstimulator integrated circuit fabrication run. Third, work continued on the microstimulator package.

Repeater Chip Revision

Based upon our work in analyzing the rectification process using the prototype Repeater Chip design, we revised the integrated circuit design to incorporate a new rectifier/local oscillator/data modulator.

Our earlier work showed the presence of a combined horizontal-vertical parasitic transistor which was inherent to the data modulator within the Repeater Chip transceiver circuit. Therefore it was necessary to use an alternate data modulation scheme which did not depend upon the use of "floating" clamp diodes. Our new circuit produces modulation of the microcoil current by simply turning on the two lower transistors which comprise the lower half of the full-wave bridge/local oscillator. This has the effect of placing a near short circuit across the microcoil, and a significant percentage of the energy contained within the parallel RLC circuit can be dissipated within 1-2 carrier cycles. The bridge transistors are then turned off and the microcoil is allowed to "coast" for the remainder of the "low" modulation period. To resume operation at the "high" modulation level, the local oscillator is turned back on by enabling the normal operation of the bridge transistors.

This method of modulation has two advantages. First, the parasitic structures, inherent to the last design are completely eliminated. Second, this method of modulation is more efficient since the local oscillator is turned on for only 1/2 of the total modulation time period. Since the power for the local oscillator is derived from the power supply hold-up capacitor, the time period for which this capacitor has sufficient voltage to operate the integrated circuit is extended. Although the modulation waveform is somewhat non-symmetrical, this poses no problem for the demodulator which will be incorporated with the transmitter.

Another feature of the revised Repeater Chip design is the incorporation of the capability to test the proposed "sleep mode" of the microtelemetry circuits. Earlier we had described the use of a sleep mode to be highly beneficial from a power supply management standpoint. Normal circuit functions such as incoming data decoding can be accomplished with a reduced power supply on the order of 3-5 volts. However, during outgoing data telemetry, it is necessary to elevate the power supply to 10-12 volts to provide sufficient hold-up capacitor voltage to allow for discharge during the operation of the local oscillator. It is wasteful from an energy standpoint to operate the microtelemetry circuit at this elevated level when outgoing telemetry is not required. The increased energy would directly impact the bulk and weight of the extracorporeal transmitter batteries.

By allowing the microtelemetry integrated circuit to operate at elevated levels only during outgoing data telemetry, the average power needed for transmitter operation can be reduced. This is to be accomplished by turning off all clocking operations within the microtelemetry circuit just prior to the onset of outgoing data modulation. During this sleep mode the current draw of the integrated circuit will be significantly reduced, and the power supply hold-up capacitor will quickly charge to a higher voltage.

This process can be enhanced by changing the operation of the extracorporeal transmitter. During normal operation, it is planned to turn the transmitter on and off at an average 50% duty cycle so that the suspended carrier modulation technique may be used in the closed loop class-E transmitter. If the transmitter is left on for longer than the average 50% time, then the current in the transmitter coil begins to rapidly rise. This has the effect of increasing the rate at which the power supply hold-up capacitor in the microtelemetry unit will charge. Therefore the rise from the normal 3-5 volts to the higher 10-12 volts can be accomplished within a few carrier cycles. Since data telemetry during which the transmitter will be turned off, will follow such a period of elevated transmitter operation, the transmitter will have more than sufficient time to recover for continued suspended carrier operation once the data telemetry period is over.

In the revised Repeater Chip design, we have incorporated several circuit modules which will permit us to test these concepts. The circuit modules have been configured with cuttable metal links to facilitate testing at the wafer level. The size of the lower bridge transistors and the number of cycles used for data modulation can be varied by cutting the metal links with an ultrasonic trace cutter. Presently this design is complete and ready to be released for layout and fabrication. We anticipate that during the next quarter, the scheduling problems which have been experienced with our foundry will be resolved and that the Repeater Chip design can proceed to fabrication.

Rework of Orbit Wafer

Due to the uncertain delivery schedule of wafers from the foundry during the first half of 1995, a parallel plan was developed to rework the microstimulator integrated circuit wafers which had been previously fabricated.

That circuit was not functional due to insufficient guarding around the rectifier diode. In earlier prototype microstimulators, an external diode had been used to bypass the internal diode. Unfortunately, the external diode also bypassed a 500 ohm series resistor needed for proper data demodulation. Also the bonding pad locations in this early layout were not compatible with the new microstimulator packaging scheme.

By cutting a trace on the integrated circuit, the external diode could be reliably removed. An external diode-resistor combination could then substitute for the defective on-chip components. It was determined that there would be sufficient room on the micro-printed wiring board within the new microstimulator package to place the external diode-resistor combination. Relocation of the integrated circuit bonding pads could be accomplished by using a gold-bump process to place new pads on the surface of the integrated circuit.

Two possible techniques were identified to cut the required trace. First, the trace could be etched. Second, the trace could be mechanically cut. The second method was chosen due to cost considerations. Martin Schwan, at the Pritzker Institute manually cut each integrated circuit on the 4 inch wafer using an ultrasonic trace cutter. The wafer has been sent to our assembly house for processing to place the gold-bump pads on the surface. At the present time the wafer is in process and we expect that it will be completed by the end of August, 1995.

The chips from this reworked wafer will have the required physical characteristics so as to permit installation in the new microstimulator package design. This is very beneficial to our progress, since efforts to assemble these stimulators will have the added advantage of producing prototype microstimulators with the new package design. When the wafers are delivered, the package techniques will have seen considerable development.

Package Development

We have continued to coordinate the design of the fabrication processes for the new microstimulator package. Springs were delivered. However, they were slightly too large for proper installation within the glass capsule. New springs are expected in the latter half of August, 1995.

Fifty Ta electrode assemblies were welded to the Pt-Ir disks. We have some concerns about the integrity of this weld. Several of the welded assemblies have been sent to the Pritzker Institute for sectioning and microscopic examination. Our first samples showed irregular weld profiles, blow holes within the disks and possible glass migration into the welded joint. We are preparing samples for examining in the SEM so that the composition of different regions within the weld can be identified.

Fifty Ir tubes were welded to the Pt-Ir disks. This procedure went fairly well after a couple of modifications to the fixtures used to press the disks onto the tubes. The thin wall of the tubes leaves little material for the weld. For future assemblies either the wall thickness of the tube could be increased or a ring of Pt-Ir wire could be used to provide filling of the joint. It appears that whichever method is used, that it is feasible to weld the disks to the tubes while keeping the tubes open.

Several mechanical samples of coils wound on ferrite core integrated circuit micro-printed wiring board assemblies were produced at the Pritzker Institute and sent to the Mann Foundation for development of the glass sealing process. The precise winding parameters are not yet known, and it may be possible to obtain some benefit from the use of a transformer rather than a

simple microcoil. When microstimulator chips are available we will be able to finalize the design and assembly process.

Suspended Carrier Patent Application

At the request of the Mann Foundation, IIT has filed a patent application for the suspended carrier transmitter modulation technique. This technology was developed under Contract NO1-NS-2-2322, and the inventors are Philip Troyk, Martin Schwan, William Heetderks and Gerald Loeb.

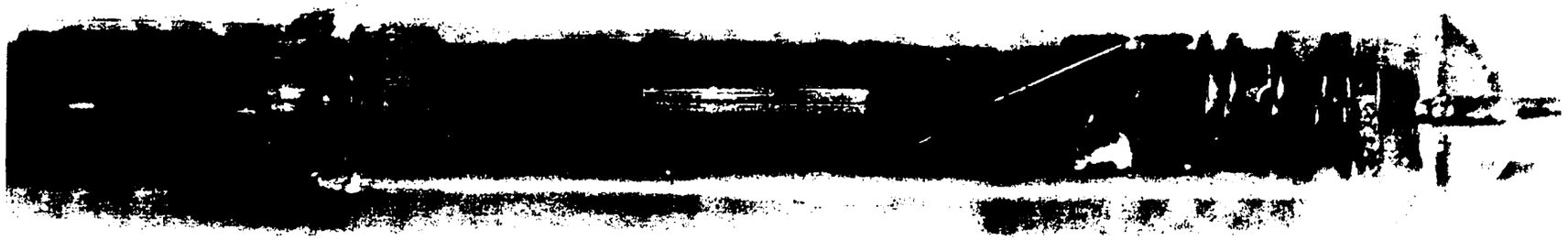

Figure 1

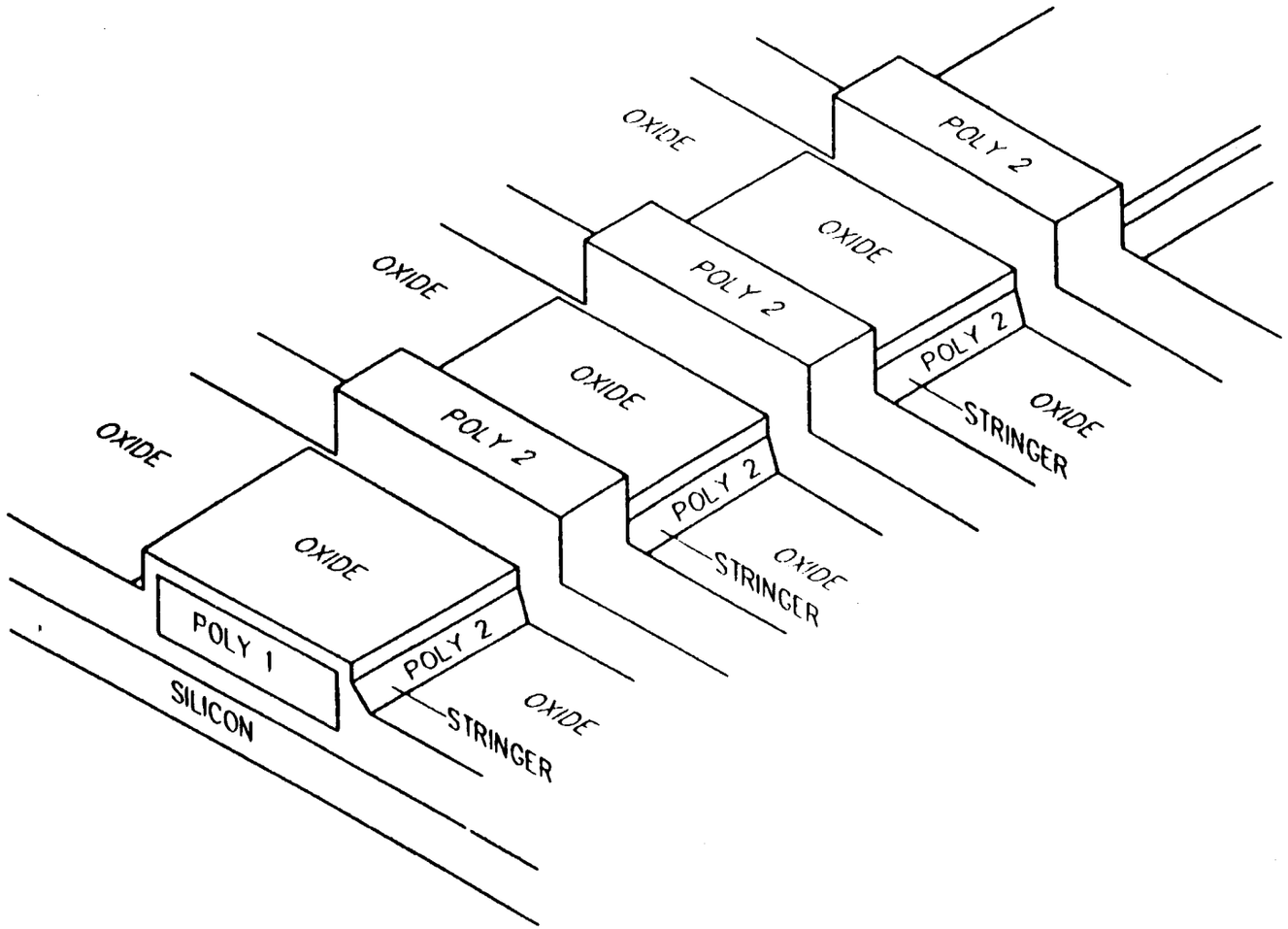
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Figure 2

MicroStimulator Bedside Controller
User's Manual

Filename: usermp1.doc and usermp2.doc in j:/guest/ustim/bedside/

MicroStimulator Bedside Controller
User's Manual

Authors: D.L. Misener, A.C. Dupont, T. Cameron, and G.E. Loeb
Version 5.15

July 5, 1995

Objectives .

This device is designed as a stand alone bedside controller used in the rehabilitation of bedridden patients with muscle hypotrophy, such as following knee or hip surgery. It uses an open loop control system to strengthen muscles. Power is provided by a standard external AC/DC power supply connected to a wall outlet.

The bedside controller outlined in this manual can control up to eight different MicroStimulators. Patient Information and Stimulation Protocol data are entered into a PC equipped with a Windows™ based graphical interface. The test-well device allows testing of individual MicroStimulators for functionality and address. During stimulation, the controller records the number of stimulation cycles sent to the MicroStimulators. Later, the PC-Windows program can upload this count from the controller and store it in the patient file. The system block diagram is shown in Figure 1.

1. Introduction

A PC graphical user interface enables the user to enter specifications for MicroStimulator pulse parameters and stimulation cycle information. The commands are sent by the PC via a RS-232 port and are received by the controller. The controller can also be setup to let the PC upload counter information.

The controller operates in 2 basic modes: PC Mode and Run Mode (Stand-alone). These modes can be set using the front panel rotary mode switch shown in Appendix 1.

PC Mode has 4 functions: Upload, Download, Test Address and Test Threshold mode. Upload mode allows the user to upload from the controller to the PC the stimulation cycle counter information. These uploaded-parameters are stored in the Patient Statistics box (described in section 3.2.1). Download mode allows the user to download from the PC to the controller stimulation pulse train and MicroStimulator parameter information. Test Address mode tests for MicroStimulators functionality and address. Test Threshold mode allows the user to determine the activation threshold of the muscle under consideration. Run Mode requires no PC interface and generates the programmed

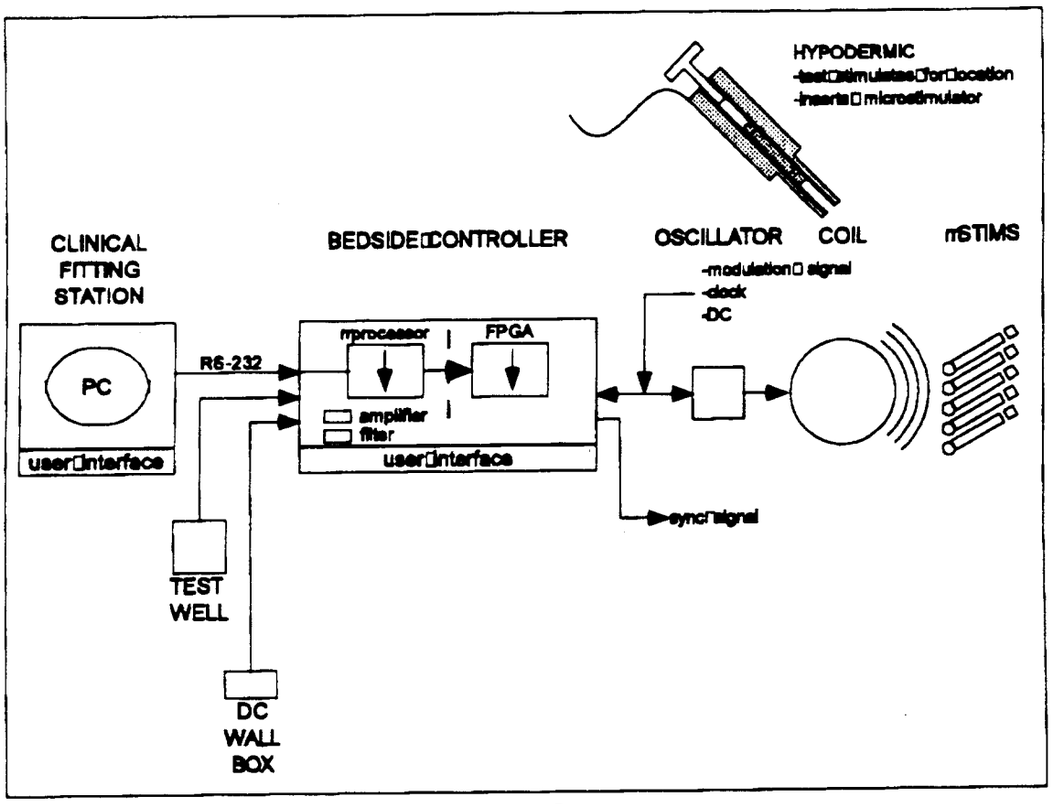


Figure 1: Block diagram of Bedside Controller System

stimulation pattern to the MicroStimulators via a modulation circuit and coil. There are a maximum of 4 different Run mode programs: Run A, Run B, Run C, and Run D.

The method to identify MicroStimulators in a given muscle is described in section 3.2.1 in the description of the MicroStimulator and Muscle Assignment screen area. This allows the user to identify each MicroStimulator with a number. These methods of identification allow the PC software to determine possible stimulation conflicts (e.g. 2 MicroStimulators, in the same muscle, being stimulated at overlapping time intervals).

The database is structured so that it can be accessed through dBase™ and Access™ softwares. The database contains five pages, one for each of the four groups of stimulator information (see section 3.2.1) plus one for patient information and muscle assignment.

The controller command language, hardware and stimulation train coding allow for future expansion and flexibility.

2. System Requirements

To download and upload information to a computer you need:

- A 386 or 486 based CPU

- Windows 3.1
- At least 4MB of memory
- A graphics monitor, colour (optional, although preferred), supported by Microsoft Windows 3.x with at least VGA (800 x 600 and 16 colors) resolution.
- A pointing device (such as a mouse) supported by Microsoft Windows

3. PC Mode

User flow chart, to demonstrate a basic fitting session, is shown in Appendix 2.

3.1 Starting PC User software

To start:

1. Start Windows by typing 'WIN' and then press ENTER
2. Start the Clinician Setup Software (CSS) by clicking on the MicroStimulator icon.

If, at any time while running the program, the controller becomes disconnected, an error message appears on the screen and indicates to the user that either the controller must be reattached to the computer, a demo of the software can be shown (no interaction with the controller), or that the session can be cancelled (as seen in Figure 2).

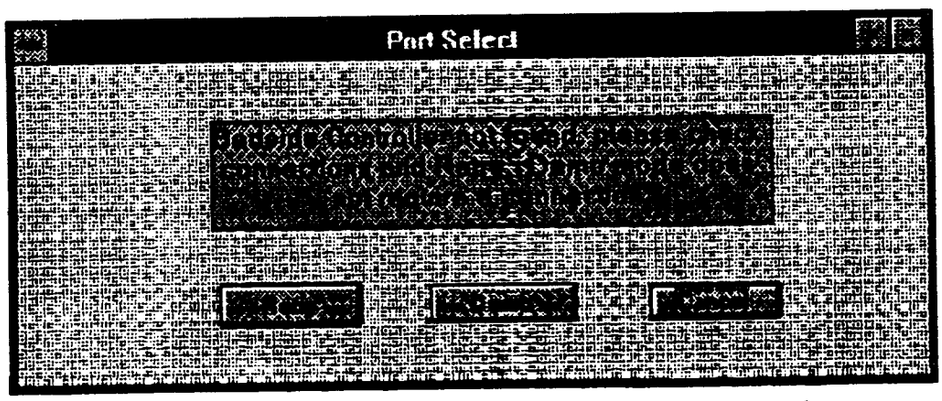


Figure 2: pop-up screen displayed when the controller is disconnected.

3.2 Clinician Setup window layout (as seen in Figure 3)

Title Bar

The title bar is used to display the program title and to move the position of the program window on the screen

Figure 3: Clinician Setup window

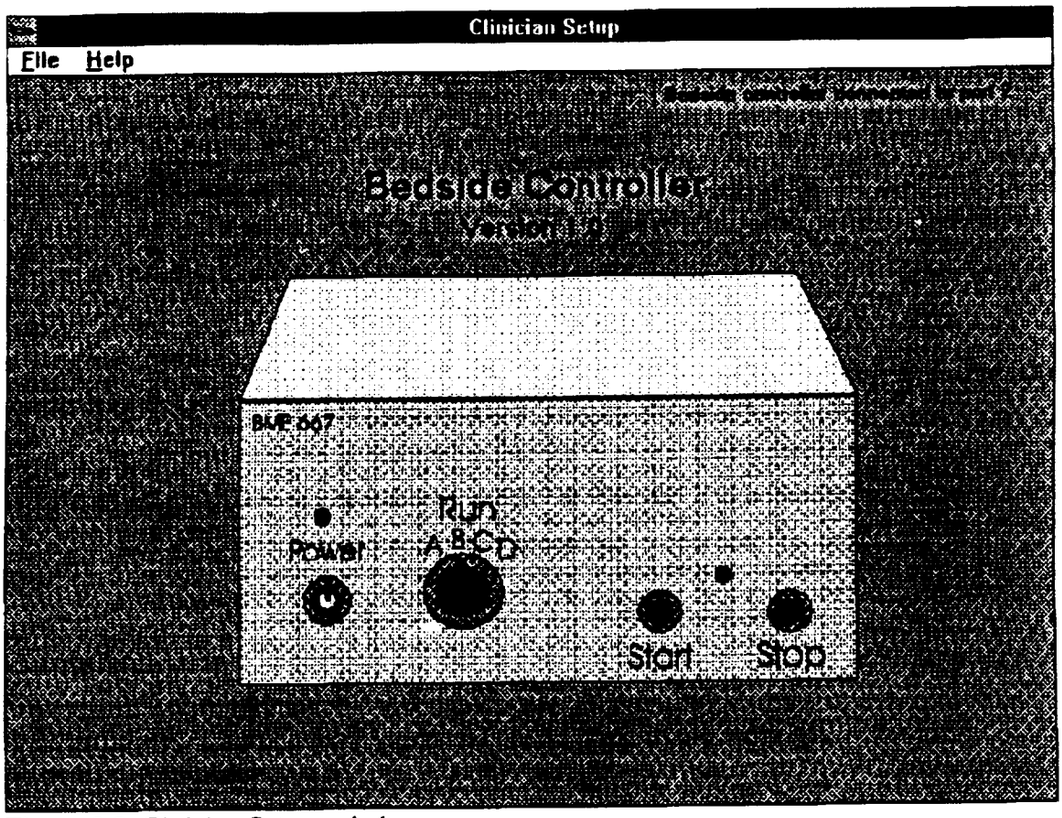


Figure 3.0: Cinician Set-up window

Menu Bar

The menu bar contains 2 drop-down menus: **File** **Help**

File

The file menu contains 3 commands (Figure 3.1):

New
Open
Exit

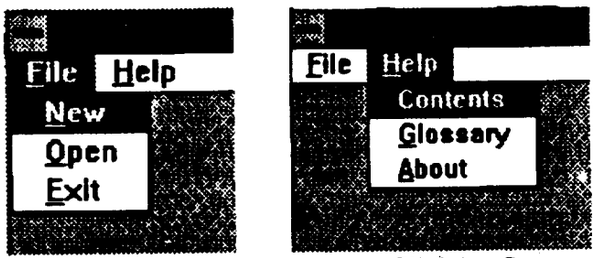


Figure 3.1: Drop-down menus in Clinician Setup window

New and **Open** Commands
These commands allow the clinician to enter, modify, download, upload, and save stimulation information by entering the **Patient History** window.

By selecting **New**, the clinician is asked to enter a name for the new file so that this new file can be created. The clinician is then given the option of using the previous muscle name settings; by choosing to do so, default muscle names will be entered on the patient Muscle Assignment screen (section 3.2.1); these muscle names can be overwritten by the clinician for correction or change. Otherwise, this screen will be blank so the clinician can enter new muscle names. Muscle names entered are retained as defaults for the next time the clinician runs the program; they can be overwritten at any time.

Exit
This command exits the program and returns the user to the windows program manager screen.

Help
By clicking on **Help**, the user can browse through the help files about the software (Figure 3.1):
Content
Glossary
About

3.2.1 Patient History (as seen in Figure 3.2)
This screen appears after selecting either **New** or **Open** from the **Clinician Setup** window.

The menu bar contains 3 drop-down menus: **File** **Test** **Help**
In addition to the three drop down menus there are 3 screen areas:
Patient Information
MicroStimulator and Muscle Assignment
Patient Statistics

File (drop-down) menu
The file menu contains 2 commands:
Save
Exit

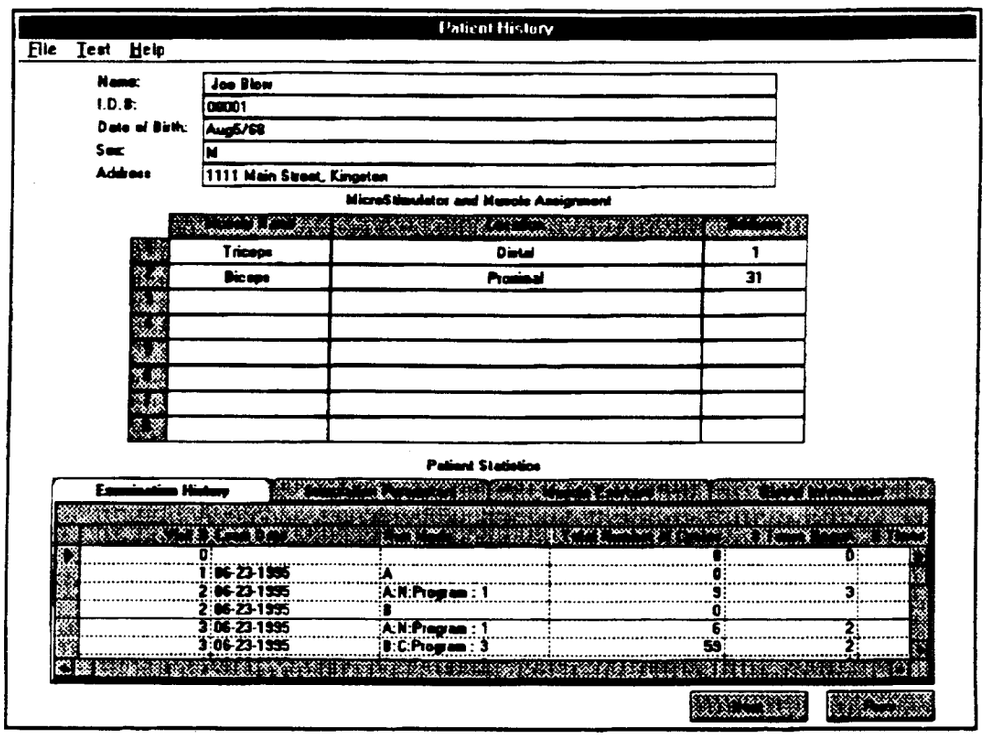


Figure 3.2: Patient History screen

Save
The **Save** command saves data under the previously chosen file name.

Exit
This command prompts the user to save the data if it has not been done and then exits the Bedside Controller software.

Test (drop down) menu
This file menu contains two commands: **Address** and **Comm Port** (Figure 3.3)

Address
The **Address** command allows the user to test or determine the address of a MicroStimulator before it is implanted into the patient. Pulses of maximum width and current are sent to the MicroStimulator located in the test well. The program cycles through all the possible addresses until it finds the one to which the MicroStimulator responds. Once the address is found, it is then displayed on the screen. This address is automatically inserted in the address column of the **MicroStimulator and Muscle Assignment** screen area on the next vacant line. If no address is found, an error message will appear; the MicroStimulator is defective and should not be used. The test well must be attached to the controller to permit the use of this option.

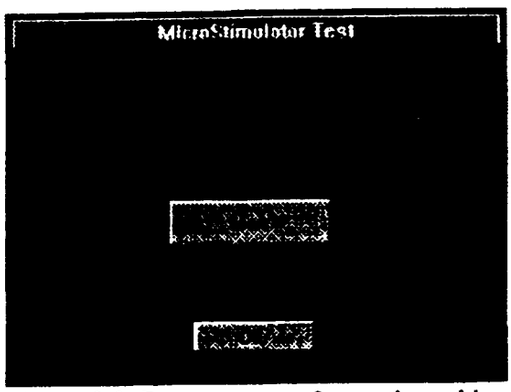


Figure 3.3: Pop-up screen for testing address

Comm Port
This command allows the user to test that the bedside controller is attached to the computer and running.

Help (drop-down) menu
This menu allows the user to browse through the help files about the software.

Patient Identification screen area
This area allows the clinician to input patient information, which includes the patient's name, file number, date of birth, sex and address.

MicroStimulator and Muscle Assignment screen area (Figure 3.4)

This area allows the clinician to input the location of each MicroStimulator in the body of the patient. To enter the muscle name in which a MicroStimulator is inserted, the user first clicks on a cell in the **Muscle Name** column where the muscle name should be entered; a **Muscle Assignment** screen appears. To select a muscle that has already been entered in the **Muscle Assignment** screen, the user clicks on the indicator (on the left side) assigned to that muscle. To enter the name of a new muscle, the user clicks on an indicator that isn't assigned to a muscle and enters the new muscle name. Clicking on **OK** enters the muscle name into the **MicroStimulator and Muscle Assignment** screen area. Clicking on **Cancel** closes the **Muscle Assignment** screen without making the change to the **MicroStimulator and Muscle Assignment** screen area. This system allows identification of multiple MicroStimulators being placed in the same muscle.

The user can also enter a description of the location of the MicroStimulator in that muscle, in the **Location** cell, as well as entering the address of the MicroStimulator manually in the **Address** cell.

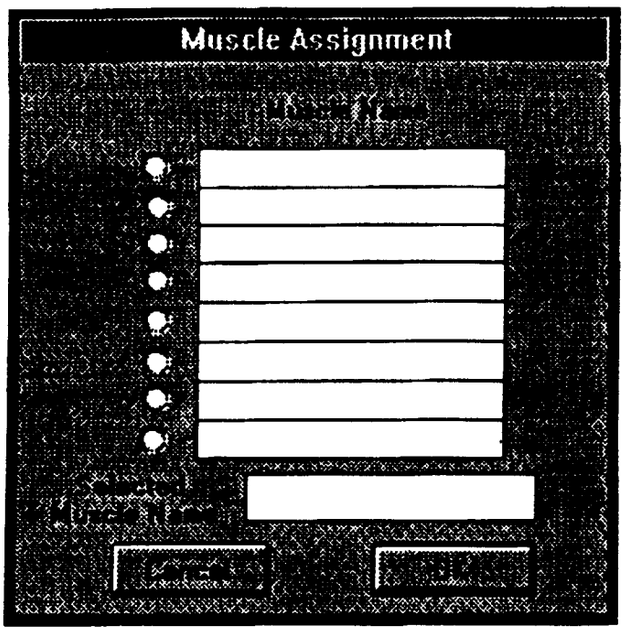


Figure 3.4: Muscle Assignment pop-up screen

Patient Statistics screen area

This is a read-only area and it displays 4 groups of stimulator information: Examination History, Stimulation Parameters, Muscle Exercise and Global Information. The user can view any group by clicking on one of the information tabs, as shown in Figure 3.5. By default, the Examination History is displayed first.

Examination History

This box displays basic information about each visit. This includes the date of the exam, the Run mode program location (A, B, C, or D, as well as non-continuous mode (N) or continuous mode (C) and the file name of the Stimulation Program), number of times the stimulation program was started and the number of interrupted program sequences, stimulation program downloaded during that session (set when there is a download in the Stimulation Program) and a comment section for the clinician to add comments or observations; the comment section is the only section where information can be entered by the clinician.

Stimulation Parameters

This box displays stimulation parameters used in the different stimulation programs for that patient. The user first selects the stimulation program using the stimulation program selection drop down menu. Once selected, the box will display all the microstim

parameters for that program (Figure 3.5): the MicroStimulator number, threshold current and pulse width, threshold multiplier, clinical current and pulse width, stimulation frequency, initial delay, ramp time, stimulation duration, cycle time and the total run time.

Muscle Exercise

This box displays information about the amount of exercise given by each MicroStimulator at each visit. This displays the visit number, the MicroStimulator number (Stim #) the number of MicroStimulator pulses, the level of exercise for a given visit and the exercise time for a given visit. The amount of exercise is the stimulation charge divided by the threshold charge, summed over all the pulses.

Global Information

This displays information relating all visits. This screen shows the MicroStimulator numbers, the total amount of exercise for all visits, the total exercise time for all visits and the total charge delivered by the microstims measured in milli-coulombs (mC). The total exercise time includes the ramp time of the stimulation pulses.

Previous button

When clicked on, this button returns to the main menu without saving any of the new information entered on the screen.

Next button

When clicked on, this button saves all the data entered by the user and opens the stimulation protocol window.

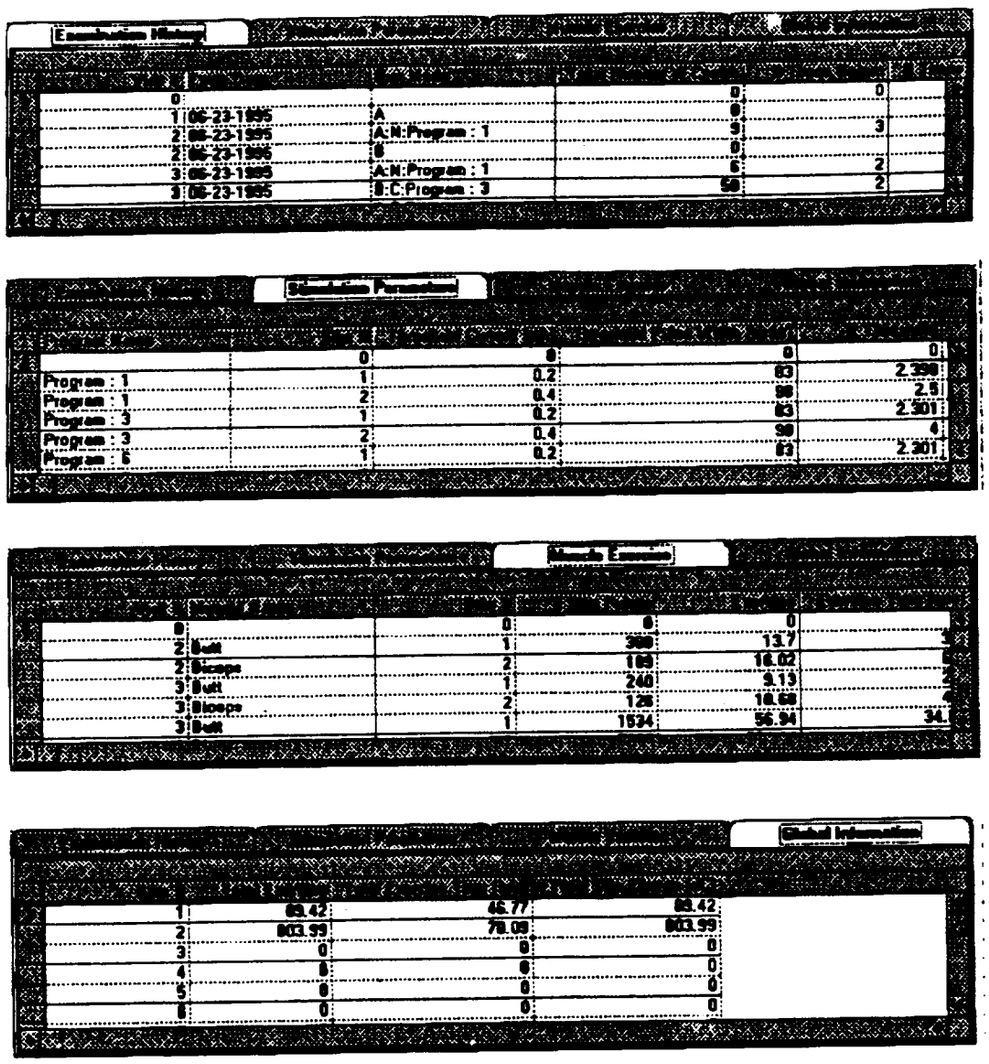


Figure 3.5: Screens from Patient Statistics

3.2.2 Stimulation Protocol (as seen in Figure 3.6)

The menu bar contains the following drop-down menus:

File **Test** **Upload** **Help**

File (drop down menu)

The file menu contains the following commands:

Open
Close
Exit

Open
This command opens a previously saved stimulation program

Close
This command saves the stimulation program and closes the Stimulation Protocol screen, returning to the patient history screen.

Exit
This command closes the Stimulation Protocol screen without saving the stimulation program, returning to the patient history screen.

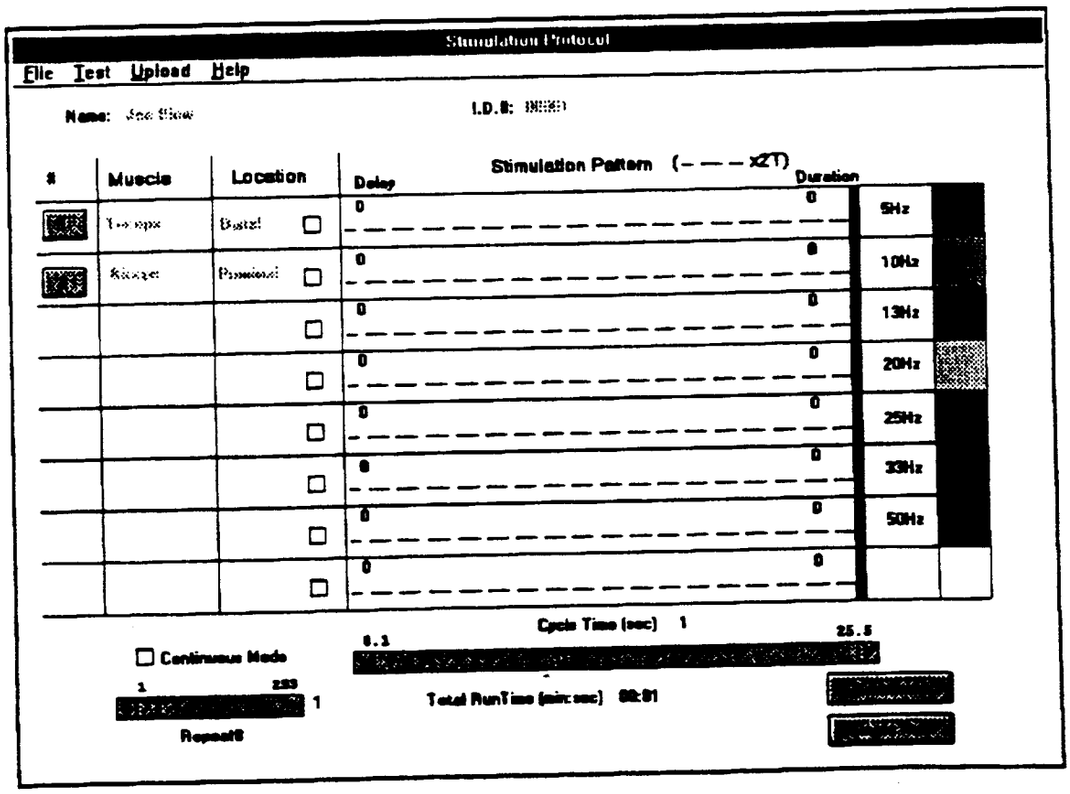


Figure 3.6: Stimulation Protocol window

1. The clinician first increases the current (default pulse width: 20 μsec.) until the threshold has been passed, as felt by palpating the muscle;
2. The clinician decreases the pulse width until the exact threshold is reached.
3. Once Threshold is determined, the user clicks on the **Threshold Set** box.

Upload

When **Upload** is selected, the counter values for all programs in the controller box are uploaded into the computer and displayed in a pop up screen (Figure 3.8). By clicking on the **Save and Close** box, the counter values are saved in the data base (located in the **Exam History** screen), the pop up screen is closed and the counters are reset to zero. The counters are reset for all run mode programs each time there is an upload to avoid adding them to elapsed usage more than once. If an attempt at downloading is made before uploading the counters, an automatic upload is made.

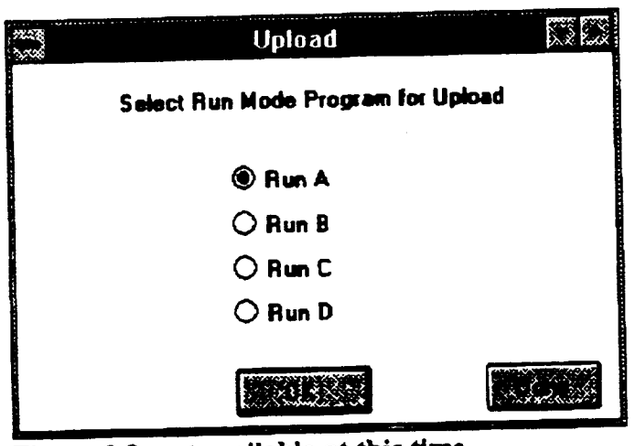


Figure 3.8: not available at this time

Help Menu (drop-down)

This menu allows the user to browse through the help files about the software.

Cycle Time scroll bar

The total time of the stimulation cycle is entered by selecting a value from the scroll bar. The default value is 1.0 sec.

Repeat # scroll bar and **Continuous mode** option

This **Repeat #** scroll bar allows the user to select the number of times the MicroStimulators will cycle through the entire stimulation cycle for one stimulation treatment. If the **Continuous mode** is selected, the MicroStimulators will cycle

through an unlimited number of stimulation cycles, until the patient stops the stimulation, by pressing the controller's **Stop** switch. In the **Continuous mode,** one stimulation cycle is counted as one treatment (**Repeat #** = 1).

Total Run Time display

Total Run Time displays the run time of a complete stimulation program; this is equal to the Cycle Time multiplied by the Repeat number. If the **Continuous mode** was selected, the indication "**cont.**" is displayed.

Stimulation Parameters boxes (Figure 3.9)

By clicking on a MicroStimulator # button, a **Stimulation Parameters** box is displayed at the bottom of the screen. If the Threshold has not been set, an error message will be displayed. The **Stimulation Parameters** box displays the Threshold Current (I) and Pulse Width (W), the Threshold Multiplier (xT), the Stimulation Current and Pulse Width, the Stimulation Frequency (pulses-per-second; pps), the Initial Delay, the Ramp Time and the Stimulation Duration. The user can change any of the clinical settings, except the Threshold Current and Pulse Width (to change the Threshold Current and the Pulse Width, the user must go back to the Test Threshold screen).

Threshold Multiplier

The software sets the default value of the Threshold Multiplier to 2 by setting the Stimulation Current to its Threshold value and the Pulse Width to twice its Threshold value. As the user changes either the Stimulation Current or the Pulse Width, the Threshold Multiplier will be recalculated and displayed; the user can also change the Threshold Multiplier directly, in which case the computer calculates values for the Stimulation Current and Pulse Width (first by increasing Pulse Width, and then if need be, by increasing the Current) and prompts the user to approve these values.

Stimulation Frequency, Initial Delay, Ramp Time and Stimulation Duration

The user can choose values for these parameters which are displayed graphically in the **Stimulation Pattern** screen area (see below). The Initial Delay is the time delay from the beginning of the cycle to the time when that MicroStimulator is activated. The Ramp Time is expressed in percentage of the Stimulation Duration and must be typed in as a integer between 0 and 100. The ramp time is included in the Stimulation Duration, and the intensity of stimulation during the ramp varies from the Threshold value to the stimulation level set (Current and Pulse Width) in a linear fashion.

Test This Train button

This command enables the clinician to test the stimulation train of this specific MicroStimulator once, in order to test that the designed stimulation train is adequate.

Test Whole Train button

By clicking on this button, the stimulation cyccle runs once so that the clinician can decide whether this is the right program for the patient. This does the same as clicking on the **Single Run** button.

When all the stimulation parameters are set, the user exits this box by clicking on **OK** or **Cancel**.

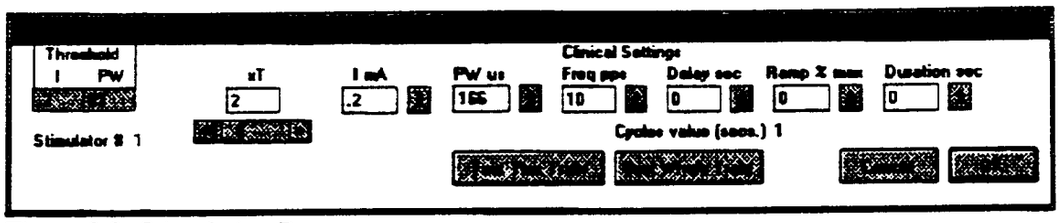


Figure 3.9: Stimulation Parameters

MicroStimulator Enabled indicators (Figure 3.10)

These indicators allow the user to select which devices will be activated during this stimulation program, without having to change the stimulation parameters.

Stimulation Pattern screen area (Figure 3.10)

This area shows graphically an entire stimulation cycle. Each MicroStimulator stimulation duration is colour-coded to show the stimulation frequency. The height of the stimulation duration represents the intensity of the stimulation (the dotted line represents 2x Threshold). With each MicroStimulator stimulation pattern, the Time Delay and Stimulation Duration are indicated by the position and size of the colored bar on the graph.

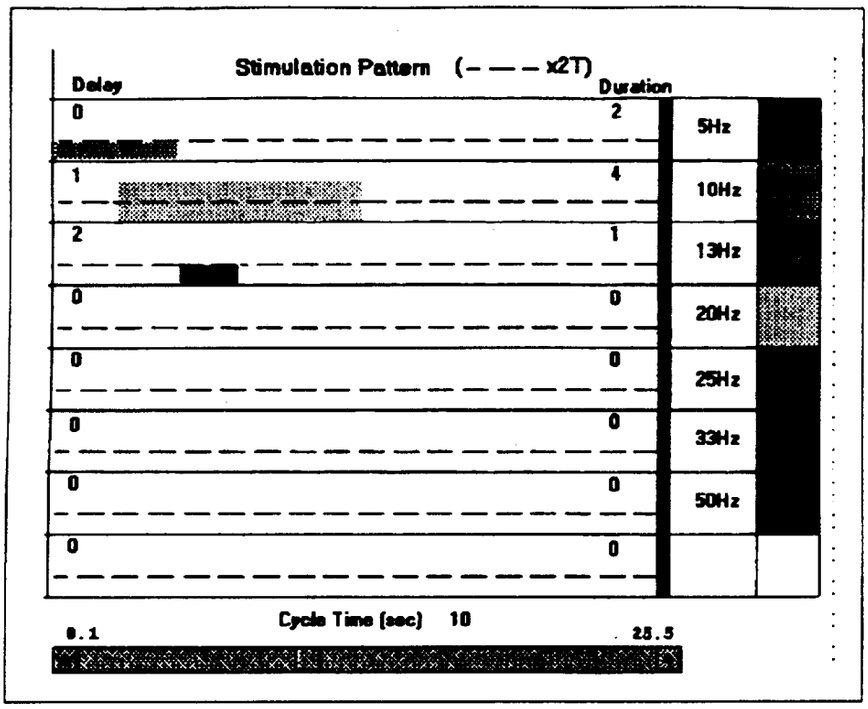


Figure 3.10: graphic area of Stimulation Protocol

Download button

By clicking on the **Download** button, first the Download Selection pop-up window opens and allows the user to select the run mode location in the controller: Run A, Run B, Run C or Run D. There is also a **disable selecter switch** that allows the user to disable the program selector switch on the box so that the patient can only use one stimulation program, the most recently downloaded one. As well, a comment box is made available to the clinician who wants to add comments to the **Examination History** of that patient; these comments are added to the database immediately. If the stimulation program is a new program or an old program that has been altered, the Save Stimulation Program pop-up window requires the user to name the program before downloading proceeds. If an attempt at downloading is made before uploading the counters, an automatic upload is made.

Single Run button

By clicking on this button, the stimulation cycle runs once so that the clinician can decide whether this is the right program for the patient.

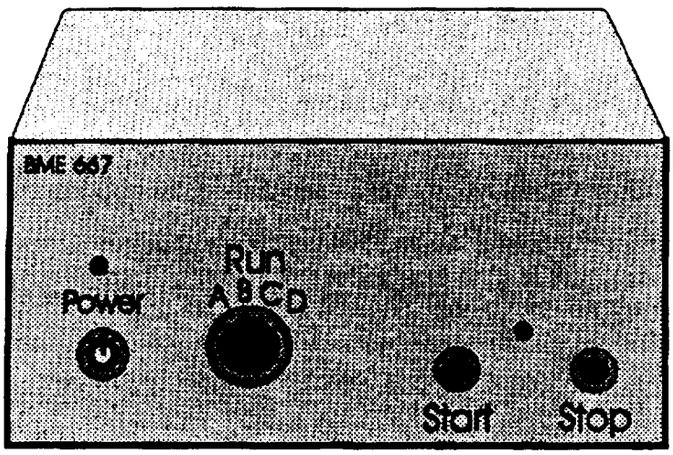
System Limitations

Table 1 lists the limitations of the controller and the software parameters:

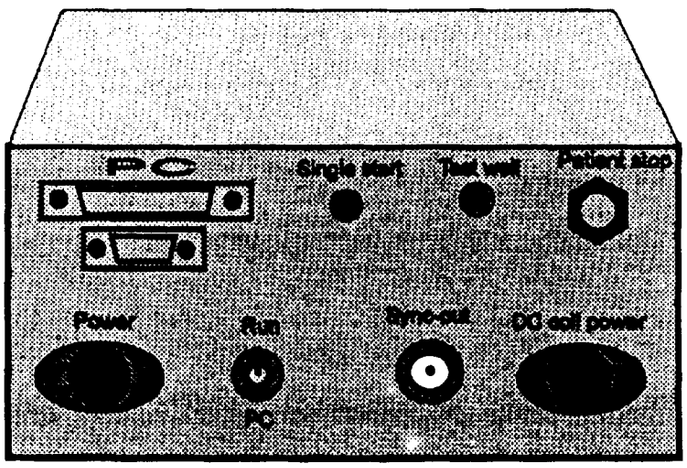
Muscle Assignment	Figure 3.4	Maximum of 8 different muscles
MicroStimulator Address	Figure 3.3	Range (0 to 255)
Pulse width (threshold)	Figure 3.7	Range (0 to 255) usec, default (100μs)
Current (threshold)	Figure 3.7	Range (0 to 30 mA) 0.1 mA steps (0 to 3 mA) and 1mA steps (3 to 30 mA)
Pulse width (clinical)	Figure 3.9	2x threshold value default
Current (clinical)	Figure3.9	threshold value default (16 setting + 1 for range)
Delay time	Figure 3.9	Range (0 to 255) 0.1 sec steps
Duration time	Figure 3.9	Range (0 to 255) 0.1 sec. steps
Cycle time	Figure 3.9	Range (0 to 255) 0.1 sec. steps.
Frequency	Figure 3.9	Range (50, 33, 25, 20, 13, 10, 5) Hz
Repeat #	Figure 3.6	Range (1 to 255) 1 cycle steps
Ramp time	Figure 3.9	Range (0 to 255) 0.01 sec. steps

Table 1. System Limitations

Appendix 1: front and back panels of the controller



Front panel



Back panel

Appendix 2: fitting session flow chart